

**Technology and Equipment  
Committee Meeting**

**August 29, 2007**

**CARDIAC CATHETERIZATION MATERIAL**

**Material Related to**

**Petition-1: Halifax Regional Medical Center**



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AUG 01 2007

Medical Facilities  
Planning Section

**Petition to the State Health Coordinating Council  
Regarding the Cardiac Catheterization Need Methodology  
For the 2008 State Medical Facilities Plan**

***Petitioner:***

Halifax Regional Medical Center  
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***Contact:***

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**PETITION**

**STATEMENT OF REQUESTED CHANGE**

Halifax Regional Medical Center (HRMC) requests the following wording change in the Proposed 2008 State Medical Facilities Plan. On page 183, change Table 9V, Shared Fixed Cardiac Catheterization Equipment Need Determinations to read:

Hospital Service System	Shared Fixed Cardiac Catheterization Equipment Need Determination	Certificate of Need Application Due Date	Certificate of Need Beginning Review Date
Halifax	1	January 15, 2008	February 1, 2008

Based upon information submitted in a special need petition, it is determined that there is a need in Halifax County for one unit of shared fixed cardiac catheterization equipment.

disease represented 290 deaths per 100,000 Halifax County residents compared to the state's rate of 204. Annually, as much as 25 percent of our population dies prematurely because of heart disease. As we move forward in health care from a transaction-based industry to one that focuses on quality outcomes and treatment of diseases, we must enhance concentration on services that help to normalize our death rates and extend quality of life.

#### Heart Disease Death Statistics

Geographical Area	Number of Deaths 2005	Death Rate 2005	Number of Deaths 2001-2005	Death Rate 2001-2005	Age-Adjusted Death Rate 2001-2005
Halifax	163	289.8	889	313.1	266.2
Northampton	95	440.5	402	369.6	276.3
North Carolina	17,681	203.6	91,056	215.9	226.8
<b>Percent of State</b>					
Halifax		142%		145%	117%
Northampton		216%		171%	122%

Source: <http://www.schs.state.nc.us/SCHS/deaths/lcd/2005/heartdisease.html>

Statewide, cardiovascular disease accounts for 38 percent of deaths, 24 percent are heart disease related. Yet, death rates are only a proxy measure for disease incidence in a population. We looked at high blood pressure as a proxy measure for prevalence of cardiac artery disease. These data are reported by the North Carolina Center for Health Statistics in its study of health risks of North Carolina adults in 2005.<sup>1</sup> In the study, Halifax and Northampton are grouped in a sector the report calls Northeast North Carolina 1. Days of reported poor health in this sector were almost twice the state average (32 compared to 18 per year). The same report shows that 42 percent of residents of Northeast 1 reported high blood pressure compared to 29 percent statewide. Four out of ten people in the sector are at risk for coronary heart disease.

#### Value of Cardiac Catheterization

Cardiac catheterization remains the modality of choice for diagnosis and treatment of advanced acute coronary syndrome. It is a key step in the diagnosis and management of coronary artery disease.

Cardiac catheterization is invasive and the procedure carries risks for patients. As technology advances, clinicians and others look for alternative ways to diagnose and treat coronary artery disease. To date, no better alternative exists. In a recent comprehensive review of the medical and invasive management of patients with acute coronary syndrome, researchers concluded that, even with its risks, invasive cardiac catheterization and revascularization are still the best

<sup>1</sup> <http://www.schs.state.nc.us/SCHS/pdf/BRFSSReport2005.pdf>

### Out Migration for Cardiac Catheterization

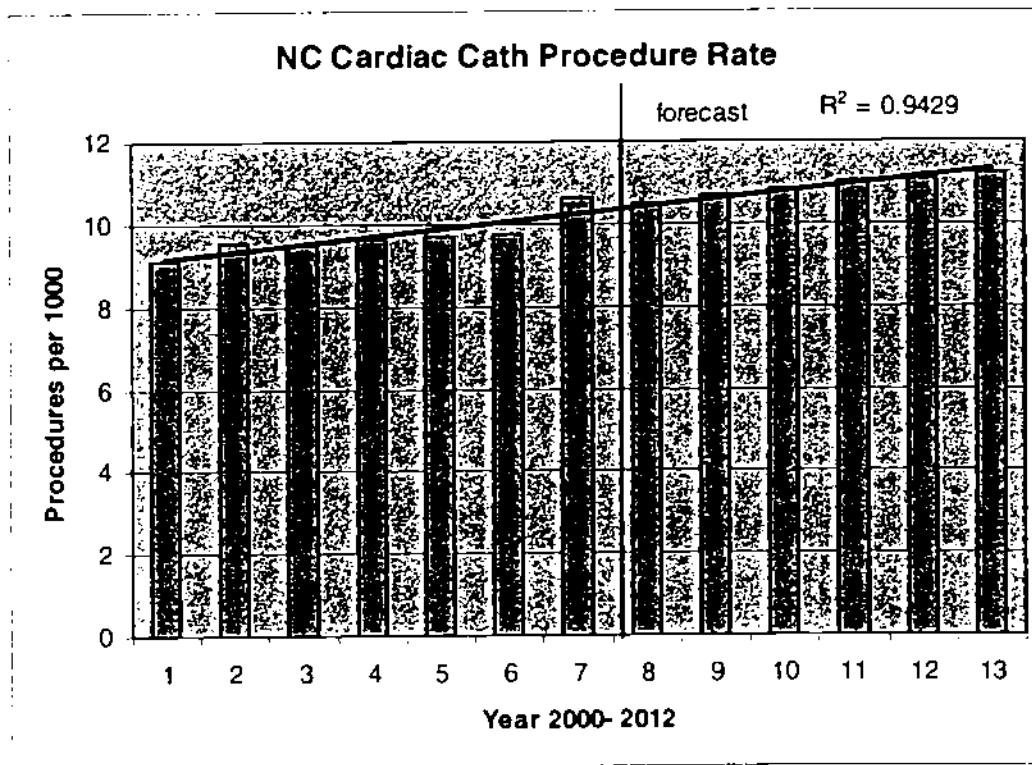
Given the high frequency of demand for cardiac catheterization, it is unreasonable to ask residents of Halifax Regional Medical Center's service area to travel an hour or more, each way, for this critical diagnostic procedure. For many, the time involved means a delay of hours or, more likely, days in getting appropriate treatment. Time involved in stabilizing the patient, determining the diagnosis, arranging medical transport, coordinating care teams at the referral hospital adds up to critical time lost for the patient for whom timely cardiac catheterization is the best solution, not to mention the strain on the referring physician. Hospital administrative and clinical leaders regularly hear frustrated reports from our referring physicians that patients have refused to leave the community to get a cardiac catheterization, when it is clearly the best medical solution.

Today, our physicians and emergency department refer cardiac catheterization patients to Greenville, Rocky Mount and Raleigh, each at least an hour away. However, many patients refuse to make that trip regardless of the exceptional quality available at these centers. For many patients, travel and cost are the ultimate barriers to care.

We have documented evidence that requiring travel outside the service area automatically deters a substantial proportion of our residents from follow up on treatment or diagnostic recommendations. This is true regardless of whether or not they have third party insurance coverage. In probing the reasons, we find that patients make these decisions for many reasons. Direct costs of the procedures or treatments play only a small role in their decision making. Patient reasons for deferral involve their perception of distance from home to the treatment center, fear of travel on the interstate and urban beltways, and distance of the referral center from family and support networks.

Some do agree to travel. Last year, 734 people from Halifax and Northampton Counties sought diagnostic catheterizations. Most went to Raleigh. These numbers represent two people a day -- more than enough to support a shared fixed cardiac catheterization lab. Indeed, the shared fixed cardiac catheterization laboratory is the ideal solution for a smaller community. With only minor modifications, technology now supports both peripheral and cardiac angiography on the same equipment

Moreover, the same disease / environmental factors that cause peripheral vascular disease cause it in the heart. Thus, with approval to offer cardiac catheterization, HRMC could address the full needs of patients who have vascular disease, and could do so with a team of competent local professionals who would collaborate on total care of patients they would see again in their practices. Patients could stay closer to their homes for the procedure. Another important benefit of the shared local lab is that pharmaceutical regimens, often a nightmare for such patients, can be coordinated locally.



#### Retention of qualified specialists in rural areas

Anyone who works in rural health care knows that recruiting and retaining qualified medical specialists is one of the most important and difficult things an administrator does. Many years experience has taught our administrative team to hold out for the best and to support them with appropriate technology. The health status of our population demands that we retain qualified cardiology staff. The numbers support a shared laboratory. We need the knowledge that a highly qualified cardiologist will share with our medical staff. For, their presence affects the entire medical knowledgebase in the community.

Scale of the need supports a decision to move now for this important service.

Halifax Regional Medical Center had mobile cardiac catheterization one day a week in 2005 and until February 2006. Then we lost our invasive cardiologist. We have now recruited another who is Board Certified, trained and experienced in both cardiac and peripheral procedures. We will resume the mobile cardiac catheterization service, but this is expensive and not a permanent solution.

We are ready to care for our community, but cannot even apply to do so unless the 2008 Plan shows a need in Halifax County.

- (2) No other fixed or mobile cardiac catheterization service is provided within the same county. "

At 8 hours per day, 52 weeks a year, 240 procedures are 4.6 procedures per day.

## **ADVERSE EFFECTS ON PROVIDERS AND CONSUMERS OF NOT MAKING THE REQUESTED CHANGE**

The only cost-effective way to make cardiac catheterization available full time in Halifax County is to start with a need in the State Medical Facilities Plan. Statute requires a Certificate of Need. There is no fixed cardiac catheterization provider in a 45-minute radius. Patients will be denied access.

A special need determination is necessary because the nature of the State Medical Facilities Plan methodology for shared fixed labs works against successfully justifying a need.

If a rural provider begins to reach 240 procedures and adds a service day or an hour in a day, the methodology ceases to show a need. When a provider does not add a day, the cardiologist gets discouraged and leaves. Patients get frustrated because they have so few scheduling options. This is clearly contrary to the Plan's Basic Principal 2.

"Expand Health Care Services to the Medically Underserved....to insure access to health care in as equitable a manner as possible..."

If this petition is not granted, we will have no choice but to contract for mobile service. In fact, we would have a better result with the methodology if we contract for less than a full day a week. This does not make sense. Mobile service adds a layer of overhead; the nature of a mobile unit means that we compromise patient privacy and comfort taking patients between the unit and the hospital; and the service gets organized around the vendor schedule, not the patient schedule. We fail to build expertise or equity locally.

The proposed special need adjustment should be considered not as a case of "if," but "when." If this proposal is not approved for inclusion in the 2008 State Medical Facilities Plan, the Halifax/ Northampton community will suffer inconvenience and deferred care for at least two and possibly three more years.

Consider the timetable. Inclusion in the 2008 Plan will result in a CON application approval by 2009 and licensure and certification delay by yet another year. In light of the fact that Halifax has a cardiologist under contract to arrive in September 2007, such a delay is not in the best interest of the patients. Some may get care on a mobile unit, if it is in town on the right day. Some will defer care. Those who elect to travel will spend substantial sums of money just getting to care. As gas costs go up and a 150- mile round trip to Raleigh costs \$26 to \$30 for

### Full lab

Similarly, a dedicated cardiac catheterization laboratory does not make sense for Halifax Regional Medical Center at this time. The level of need in the service area is too small, making the required market share too high to justify the capital cost associated with a dedicated cardiac catheterization laboratory.

### Mobile

As an interim step, Halifax Regional Medical Center is returning to the mobile cardiac catheterization laboratory solution. Halifax is in the process of making arrangements with Duke University Medical Center to have a mobile laboratory on site one day a week. Given our past experience and demand from our primary care physicians, we have no doubt that the numbers will reach 240 procedures per 8-hour day per year. If we add a second day, the current wording of the methodology, would be hurting our chances to get a shared lab. A second day would raise the threshold to 480 procedures; again putting need out of reach.

Mobile is at best an interim solution. It demonstrates the need, it shows our referral community that we can safely perform the procedures; it gives us a way to keep our cardiologist.

It is inefficient. It adds overhead. It is always at risk of a truck breakdown and / or damage to the equipment on the road.

### CT Angiography

Multi-slice (64) computed tomography is an effective tool in coronary artery disease diagnosis. It reduces the need for diagnostic cardiac catheterization by only five percent. Its primary role is as a substitute for nuclear stress tests.<sup>6</sup>

### Shared lab

As noted above, this is the efficient solution for our community. It makes the service available more days a week. It will let us address the entire problem of vascular disease in a single patient. It will not require us to isolate treatment of vascular disease to one part of the body.

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<sup>6</sup> Fine, Jeffrey, View Public Comment for Computer Topographic Angiography ( CAG-00385N), 6/15/2007

## **TA 6.57 Computed Tomography Angiography (CTA) for Coronary Artery Disease**

**Effective Date:** Oct 2006**Revised:****Next Review:**

**Policy:** Computed Tomography Angiography (CTA) for coronary artery disease is a new and promising technology, but remains investigational, unproven, and experimental. HPHC will cover on a case by case basis after review by NIA

**Process:** Reviewed by NIA.

### **The Technology and the Clinical Circumstances for which it is Being Evaluated:**

About 13 million people in the United States have coronary artery disease (CAD). It is the leading cause of death in both men and women. Each year, more than half a million Americans die from CAD. (National Heart, Lung and Blood Institute)

Computed Tomography Angiography (CTA) has been proposed as a noninvasive alternative to invasive coronary angiography. Compared to catheter angiography, which involves placing a sizable catheter and injecting contrast material into a large artery or vein, CTA is a 'noninvasive' outpatient procedure. The procedure for computed tomography angiography (CTA) is to inject a contrast material into a small peripheral vein by using a small needle or catheter to visualize blood flow in arterial and venous vessels throughout the body. The images are generated by a computer synthesis of x-ray transmission data obtained in many different directions in a given plane. Negative findings on CTA obviate invasive angiography, but those with positive CTA findings (i.e., significant stenosis) would still need to be confirmed by invasive coronary angiography. In this case, a high negative predictive value for cardiac CTA would be important.

CTA offers important advantages over conventional angiography, which depicts only the vascular lumen. With CTA, additional information is provided, including vessel wall thickness, relationship to adjacent structures, enhanced depiction of the venous anatomy, and parenchymal information of the target organ and other structures within the scan range and field of view (American College of Radiology, July 2001). The disadvantages of CTA that some studies have shown is that multislice CT exposes the patient to more radiation than single-slice CT and x-ray angiography, and also CTA uses nephrotoxic iodinated contrast material. American Society of Nuclear Cardiology (ASNC) states that the obstacles for routine use of CT angiography are multifactorial and include: 1) substantial movement of the coronary arteries during the cardiac cycle and the limitations of temporal resolution of MDCT technology that involves rapid rotation of heavy collimated detectors; 2) spatial resolution limitations; 3) artifacts caused by overlying calcium or stents that can obscure the presence of luminal narrowing; 4) the need for a slow and regular heart rate during the bolus first-pass acquisition. All of these limitations can reduce the portion of the coronary arterial tree that can be accurately scrutinized and renders this technique, currently, as a research tool. (9)

### **Supporting Information:**

#### *1. Technology Assessment:*

Hacker et al conducted Controlled clinical trials to compare conventional coronary angiography to spiral multidetector CT (MDCT) angiography in detection and validation of coronary lesions. They did a retrospective analysis that compared the accuracies of MDCT angiography and myocardial perfusion imaging (MPI) in the detection of hemodynamically relevant lesions of the coronary arteries. Twenty-five patients with suspected or known coronary artery disease were studied. Electrocardiographically gated MPI and 16-MDCT angiography were performed. Ninety-nine coronary vessels were analyzed, and the quality of MDCT angiography images was assessed for 330 coronary segments. Coronary artery diameter was interpretable for 231 (70%) of 330 segments, whereas in 99 (30%) of 330 segments, vessel diameter could not be evaluated because of heavy calcifications, blurring, motion artifacts, or intracoronary stents. MDCT angiography detected stenoses  $\geq 50\%$  in 15 of 100 coronary arteries. Eight (53%) of 15 stenoses  $\geq 50\%$  showed reversible or fixed perfusion defects in the corresponding myocardial areas on MPI. Sensitivity, specificity, and negative and positive predictive values were 100%, 87%, 100%, and 29%, respectively, for the ability of MDCT angiography to detect reversible perfusion defects in the corresponding myocardial areas. The authors concluded that compared with MPI alone, CTA added important morphologic information, but **MPI remains mandatory** for evaluating the functional relevance of coronary artery lesions.

- Gaudio C, Mirabelli F, Alessandra L, Nguyen BL, Di Michele S, Corsi F, Tanzilli G, Mancone M, Pannarale G, Francone M, Carbone I, Catalano C, Passariello R, Fedele F. *Noninvasive assessment of coronary artery stenoses by multidetector-row spiral computed tomography: comparison with conventional angiography.* Eur Rev Med Pharmacol Sci. 2005 Jan-Feb;9(1):13-21.

Gaudio et al conducted a clinical trial to analyze the diagnostic accuracy of multi-detector row spiral computed tomography (MDCT) in determining mid- to high-grade coronary artery stenoses ( $> 50\%$ ). Sixty-nine patients with suspected CAD were referred to MDCT coronary angiography and mean values of MDCT coronary narrowings were compared to quantitative coronary angiography. MDCT correctly detected 95 of 123 coronary lesions (**sensitivity 77.2%**) and absence of stenoses was correctly identified in 388 of 426 segments (**specificity 91%**). The sensitivity for the left main (LM), the left anterior descending artery (LAD), the right coronary artery (RCA) and the proximal tract of the circumflex artery (LCX) was 100%, 86.5%, 69.8% and 80% respectively. Classification of patients as having 1-vessel, 2-vessels, 3-vessels or left main disease was accurate in 75.4% (46/61) of patients. The authors concluded that MDCT technology, combined with heart rate control, allows **reliable noninvasive detection of hemodynamically significant CAD**.

- Leber AW, Knez A, von Ziegler F, Becker A, Nikolaou K, Paul S, Wintersperger B, Reiser M, Becker CR, Steinbeck G, Boekstegers P. *Quantification of obstructive and nonobstructive coronary lesions by 64-slice computed tomography: a comparative study with quantitative coronary angiography and intravascular ultrasound.* J Am Coll Cardiol. 2005 Jul 5;46(1):147-54.

Leber and colleagues did a clinical trial to determine the diagnostic accuracy of 64-slice computed tomography (CT) to identify and quantify atherosclerotic coronary lesions in comparison with catheter-based angiography and intravascular ultrasound (IVUS). 59 patients were scheduled for coronary angiography due to stable angina pectoris. A contrast-enhanced 64-slice CT was performed before the invasive angiogram. In a subset of 18 patients, IVUS of 32 vessels was part of the catheterization procedure. In 55 of 59 patients, 64-slice CT enabled the visualization of the entire coronary tree with diagnostic image quality (American Heart Association 15-segment model). The overall correlation between the degree of stenosis detected by quantitative coronary angiography compared with 64-slice CT was  $r = 0.54$ . **Sensitivity** for the detection of stenosis  $< 50\%$ , stenosis  $> 50\%$ , and stenosis  $> 75\%$  was **79%, 73%, and 80%**, respectively, and **specificity was 97%**. In comparison with IVUS, 46 of 55 (84%) lesions were identified correctly. The mean plaque areas and the percentage of vessel obstruction measured by IVUS and 64-slice CT were 8.1 mm<sup>2</sup> versus 7.3 mm<sup>2</sup> ( $p < 0.03$ ,  $r = 0.73$ ) and 50.4% versus 41.1% ( $p < 0.001$ ,  $r = 0.61$ ), respectively. Leber et al concluded that Contrast-enhanced 64-slice CT is a **clinically robust modality** that allows the identification of proximal coronary lesions with excellent accuracy. Measurements of plaque and lumen areas derived by CT

- *Unicare*: (April 2005):  
Computed tomography angiography is considered **investigational/not medically necessary** for the evaluation of coronary arteries, including, but not limited to the following:
  - Screening for coronary artery disease (CAD), either in asymptomatic subjects or as part of a preoperative evaluation
  - Diagnosis of CAD, in patients with acute or non-acute symptoms, or after a coronary intervention
  - Delineation of a coronary artery anatomy or anomaly<http://medpolicy.unicare.com/policies/RAD/CTA.html>

### 3. Governmental/Regulatory Agencies:

- *FDA*: Multiple manufacturers have received FDA 510(k) clearance to market MDCT machines equipped with at least 16 detector rows and at least two models of EBCT machines have been cleared through FDA 510(k) clearance. Intravenous iodinated contrast agents used for CTA have also received FDA approval. (7)
- *CMS*: No national coverage policy specifically addressing CTA for coronary artery evaluation was found. CMS has issued a National Coverage Determination regarding CT scanning in general. This policy states that diagnostic examinations of the head and other parts of the body performed by CT scanners are covered if the medical and scientific literature and opinion support the effective use of a scan for the condition, and the scan is: reasonable and necessary for the individual patient; and performed on a model of CT equipment that has been approved by the FDA. (5)
- *National Heritage Insurance company (Northeast CMS)*: March 2006 (6)

#### Indications of Coverage:

The MDCT angiography of the heart may be employed in a variety of clinical settings:

1. Facilitation of the diagnostic cardiac evaluation of a patient with chest pain syndrome (e.g. chest pains, anginal equivalent, angina). Depending on the clinical presentation, the MDCT for coronary artery evaluation may precede a perfusion stress test, or it may be used to clarify a perfusion stress test that is non-diagnostic, equivocal, or is inadequate in explaining the patient's symptoms.
2. Facilitation of the management decision of a symptomatic patient with known coronary artery disease. (eg., post-stent, post CABG) when the results of the MDCT may guide the decision for repeat invasive intervention.
3. Assessment of suspected congenital anomalies of coronary circulation or great vessels.
4. Assessment of the symptomatic patient when presentation is suspicious of aortic dissection.
5. Facilitation of diagnostic evaluation and management of an asymptomatic patient at high cardiovascular risk (e.g. newly diagnosed severe left ventricular systolic dysfunction of unknown etiology).
6. Assessment of coronary artery anatomy prior to non-coronary cardiac surgery (e.g. valve repair or replacement, ascending aortic aneurysm or dissection repair).
7. Facilitation of diagnostic evaluation and management of patients with implantable cardiac devices (pacemakers, ICDs) who are about to undergo, or have undergone therapeutic electrophysiological procedures, in which detailed anatomical knowledge of the atria, pulmonary veins, and cardiac veins is required.

#### Limitations of Coverage:

1. The test is never covered for screening, i.e., in the absence of signs, symptoms of disease.
2. The selection of the test should be made within the context of other testing modalities so that the resulting information facilitates the management decision, not merely adds a new layer of testing.
3. Coverage of this modality for coronary artery assessment is limited to devices that process thin, high resolution slices (1 mm or less). The multidetector scanner must have at least 16 slices per second capability.
4. The administration of beta blockers and the monitoring of the patient by a cardiologist during the MDCT are not separately payable services.
5. All studies must be ordered by a physician or a qualified non-physician practitioner.

- 10) Hoffmann MH, Shi H, Schmitz BL, Schmid FT, Lieberknecht M, Schulze R, Ludwig B, Kroschel U, Jahnke N, Haerer W, Brambs HJ, Aschoff AJ. *Noninvasive coronary angiography with multislice computed tomography*. JAMA. 2005 May 25;293(20):2471-8.
- 11) Hacker M, Jakobs T, Matthiesen F, Vollmar C, Nikolaou K, Becker C, Knez A, Pfluger T, Reiser M, Hahn K, Tiling R. *Comparison of spiral multidetector CT angiography and myocardial perfusion imaging in the noninvasive detection of functionally relevant coronary artery lesions: first clinical experiences*. J Nucl Med. 2005 Aug;46(8):1294-300.
- 12) Gaudio C, Mirabelli F, Alessandra L, Nguyen BL, Di Michele S, Corsi F, Tanzilli G, Mancone M, Pannarale G, Francone M, Carbone I, Catalano C, Passariello R, Fedele F. *Noninvasive assessment of coronary artery stenoses by multidetector-row spiral computed tomography: comparison with conventional angiography*. Eur Rev Med Pharmacol Sci. 2005 Jan-Feb;9(1):13-21.
- 13) Leber AW, Knez A, von Ziegler F, Becker A, Nikolaou K, Paul S, Wintersperger B, Reiser M, Becker CR, Steinbeck G, Boekstegers P. *Quantification of obstructive and nonobstructive coronary lesions by 64-slice computed tomography: a comparative study with quantitative coronary angiography and intravascular ultrasound*. J Am Coll Cardiol. 2005 Jul 5;46(1):147-54.
- 14) ACCF/ACR/SCCT/SCMR/ASNC/NASCI/SCAI/SIR 2006 Appropriateness Criteria for Cardiac Computed Tomography and Cardiac Magnetic Resonance Imaging. Journal of the American College of Cardiology Vol. 48, No. 7, 2006. <http://www.acc.org/qualityandscience/clinical/pdfs/CCT.CMR.pdf>

REC'D @ July 24  
2007 GREENVILLE  
PUBLIC HEARING

**Public Hearing Comments on Proposed 2008 State Medical Facilities Plan  
Cardiac Catheterization**

**July 24, 2008, 1:30 PM**

**Pitt County Office building**

**Greenville, NC**

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JUL 24 2007

MEDICAL FACILITIES  
PLANNING SECTION

Presented by  
William Mahone,  
President and CEO  
Halifax Regional Medical Center

My name is William Mahone, and I am President and CEO of Halifax Regional Medical Center, in Roanoke Rapids and I am here today on behalf of the many people in Halifax and Northampton Counties. We're very proud of our 206-bed Medical Center, our Medical Staff and their services, and we work with limited resources to provide the best and most accessible health care to the 158,000 residents in our service area.

My colleague, Michael Joyner, and I traveled here today to emphasize the importance of our message regarding a proposed special need determination for a shared fixed cardiac catheterization laboratory in Halifax County. I assume you know of our location.

Roanoke Rapids is an hour north of Rocky Mount on I-95, near the Virginia border. Our communities are struggling with the economic shift out of textiles and into the next new industry. Meanwhile we've had years of farm work, manufacturing, and low income jobs that have given us a legacy of chronic diseases. On the coastal plain, like parts of the mountains, we have people who live on dirt roads, in homes without electricity. Heart disease rates are 50 percent above the state average and we rank number two in poverty.

Our service area is very rural. While more urban residents become accustomed to driving on interstates, these are intimidating to the patients in our rural areas. We have documented cases of patients who had third party coverage and who refused to travel to Raleigh to get cardiac catheterization recommended by their physicians. In 2006 we had four patients who failed their diagnostic cardiac cath and refused to travel to Raleigh for

We are not asking for an exception. We are asking that the State Health Coordinating Council permit us to make better use of an existing resource. We have applied for equipment to improve peripheral angiography diagnosis and treatment at the hospital and have demonstrated that that investment can pay for itself. With only a small additional investment, we can expand the equipment's capacity and use it for cardiac catheterization. But to do so, we will need Certificate of Need approval, and that approval requires the need be identified in the State Medical Facilities Plan. The shared fixed laboratory offers a very efficient way to serve rural patients.

Halifax Regional Medical Center has demonstrated that it can provide cardiac catheterization safely. With the mobile service we reached days when our cardiologist did six to eight procedures. The threshold for a shared fixed lab is only 4.6 procedures a day (240/52). Help us maintain our momentum.

We considered alternatives such as waiting another year. But when we considered the impact of waiting, the delay was unacceptable. Even with a need listed in the 2008 Plan, it will be 2010 before we could apply and receive Certificate of Need approved. We are serving a population that has already waited too long. They have advanced cardiac disease. Please do not delay another year our ability to make these services available to our patients. Our quality systems are in place and our staff is trained. We have recruited an exceptional physician and have arranged the required back up. Making us wait only increases the overhead we pay to a mobile provider and restricts the service to one day a week. Cardiac catheterization rates have been steadily increasing in North Carolina, about 2 percent a year for the past seven years. Permitting us to do a limited number of procedures at Halifax Memorial Hospital will not hurt any of the existing programs. Increases in use rate, and population will more than offset any procedures that might remain in Halifax rather than travel outside.

**Public Hearing Comments on Proposed 2008 State Medical Facilities Plan  
Cardiac Catheterization**

**August 1, 2007, 1:30 PM**

**Jane S. McKimmon Center**

**Raleigh, NC**

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AUG 01 2007

Presented by  
Diane Barlow  
Vice-President

Medical Facilities  
Planning Section

Halifax Regional Medical Center

My name is Diane Barlow, and I am Vice-President of Halifax Regional Medical Center, in Roanoke Rapids. I am here today on behalf of the many people in Halifax and Northampton Counties. We are very proud of our 206-bed Medical Center, our Medical Staff and their services, and we work with limited resources to provide the best and most accessible health care to the 158,000 residents in our service area.

My colleague, Karen Daniels, and I traveled here today to emphasize the importance of our message regarding a proposed special need determination for a shared fixed cardiac catheterization laboratory in Halifax County. Roanoke Rapids is an hour north of Rocky Mount on I-95, near the Virginia border. Our communities are struggling with the economic shift out of textiles and into the next new industry. Meanwhile we've had years of farm work, manufacturing, and low income jobs that have given us a legacy of chronic diseases. On the coastal plain, like parts of the mountains, we have people who live on dirt roads and in homes without electricity. Heart disease rates are 50 percent above the state average and we rank number two in poverty.

Our service area is very rural. While more urban residents become accustomed to driving on interstates, these are intimidating to the patients in our rural areas. We have documented cases of patients who had third party coverage and who refused to travel to Raleigh to get cardiac catheterization recommended by their physicians. In 2006 we had four patients who failed their diagnostic cardiac cath and refused to travel to Raleigh for

needed care. Barriers are many including travel, transportation, drivers and their availability to drive and wait for services of others. Health literacy, i.e. reading and understanding instructions, is a problem for many in our area.

In 2005, we developed a cardiac catheterization program using a mobile unit from MedCath. We had clinical back up from WakeMed and Pitt County Memorial Hospital. The number of catheterizations climbed quickly and we were well on our way to reaching the threshold that would qualify the county for a shared fixed lab this year, when our cardiologist left the area. We have recruited a new cardiologist, Dr. Celoo, and have done some things organizationally to assure that he will stay – and you can help us with that important goal. The mobile cardiac catheterization service will start up again in September. This time Duke will be the vendor. Back up arrangements will be the same.

We have recently strengthened our Management Team and are resolved to provide the services most needed by our community. With almost 2,000 cardiac catheterizations in our service area every year, it will take only a 12 percent market share to sustain a strong shared fixed cardiac catheterization laboratory. More importantly, offering both cardiac and peripheral vascular angiography in Roanoke Rapids will permit our medical staff to treat the whole patient in their home community. Ms. Daniels will address more clinical issues.

I understand the role of the State Planning process in containing costs and minimizing duplication. But it is equally important to consider the second basic plan principle, - improving access. North Carolina's urban centers: Charlotte, Asheville and Raleigh are growing very rapidly. They share the same climate as the state's rural communities, but have many more medical resources. We can do a better job of sustained growth in North Carolina if we think about spreading resources in a way that makes the outlying communities attractive. Rural communities have attractions, in our case Lake Gaston, and we have retirement communities. To support these and long time residents, we need the technology to make our medical support system attractive to physicians, nurses and health care technologists.

We are not asking for an exception. We are asking that the State Health Coordinating Council permit us to make better use of an existing resource. We have applied for equipment to improve peripheral angiography diagnosis and treatment at the hospital and have demonstrated that that investment can pay for itself. With only a small additional investment, we can expand the equipment's capacity and use it for cardiac catheterization. But to do so, we will need Certificate of Need approval, and that approval requires the need be identified in the State Medical Facilities Plan. The shared fixed laboratory offers a very efficient way to serve rural patients.

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Anyone who has worked with a mobile service knows the drawbacks. Trucks will break down, equipment is jostled and most importantly, the equipment is not there when the patients most need it.

I also want to comment on the State Plan's methodology for calculating need for a unit of shared fixed cardiac catheterization equipment as it is imperfect. The methodology sets a moving target based on the number of 8-hour days of mobile service we have. If we have one day of service a week, the target is 240 procedures. If we add a second 8-hour day, or an additional hour to an existing day, the target moves up 240 procedures a year for each eight hours of service per week. This is not accurate or fair. We ask that you be accurate and fair and give us a chance to make efficient use of our resources.

We will be submitting a formal petition later this summer.

Now, I would like to introduce our Vice-President of Nursing, Karen Daniels.

**Public Hearing Comments on Proposed 2008 State Medical Facilities Plan  
Cardiac Catheterization**

**August 1, 2007, 1:30 PM**

**Jane S. McKimmon Center**

**Raleigh, NC**

Presented by  
Karen Daniels, RN,  
Vice President and CNO  
Halifax Regional Medical Center

Good afternoon, my Name is Karen Daniels. I am a registered Nurse with 27 years of experience and Vice President of Nursing Services at Halifax Regional. I have had the great good fortune of being a military wife and have practiced my profession all over the world. As a nurse specializing in critical and emergency care, I have first hand knowledge of the devastation caused by vascular disease including heart attack, stroke, as well as loss of limb. I have also seen how often it is under treated particularly in rural communities such as ours.

Halifax Regional will be working closely with an interventional cardiologist who also has received training in cardiac and vascular disease in eastern North Carolina. Dr. Geloo's training in both coronary and peripheral vascular disease will offer a new and unique perspective to Roanoke Rapids and the population within the surrounding communities.

Atherosclerosis is a systemic disease that leads to devastating acute and long term consequences. While the disease can affect multiple vascular beds including the heart, kidneys, legs, and brain, the disease process is exactly the same in these varied areas. Most patients with vascular disease manifest their disease in multiple vascular beds; therefore such patients may go to a cardiologist for coronary disease, a neurologist for carotid artery disease, and a vascular surgeon for leg pain as a result of poor circulation. This approach may delay global diagnosis and more importantly perhaps, disease modifying treatment. Increased awareness of disease in one vascular bed leads to early diagnosis of the disease manifestation in another vascular bed. Dr. Geloos' unique training will afford us the opportunity to focus on the disease and the patient as a whole rather than focusing on individual processes.

This approach to disease management is an important one in that all of these diseases are interrelated. A patient with poor circulation to the lower extremities is at an increased risk for heart attack and death; conversely a patient with coronary disease is at significant risk for stroke. These relationships are well documented by research and epidemiology trials. In many cases these disease states will require invasive angiography for definitive diagnosis.

Approval of an angiography suite and cardiac catheterization laboratory at Halifax Regional will provide leading edge technology for diagnosis and potentially definitive treatment, services currently unavailable for our patients. As a result of his training Dr. Geloo will be able to offer patients on-site revascularization for arterial insufficiency in select patients for whom such procedures can be performed safely. Complex patients will continue to be referred to tertiary care facilities. Peripheral arterial disease is routinely under-diagnosed and it is our belief that neighboring tertiary facilities will see an increase in the number of referrals from Halifax as a result of our expanded focus on atherosclerosis.

Cardiac catheterization will be a very important addition to the services we provide at Halifax Regional. Approximately one third of all patients undergoing diagnostic angiography actually undergo angioplasty or stenting during the same procedure. Therefore the majority of these patients undergo only the diagnostic procedure. In 2005 and until April 2006, Halifax Regional Medical Center had mobile cardiac catheterization one day a week. The program was well accepted by the community and referring physicians and the number of procedures grew rapidly. Our patients reflected the national predictions and we were very safe and successful in providing the service. Last year, 734 people from Halifax and Northampton Counties went elsewhere for diagnostic catheterizations. This is two people a day -- more than enough to support a shared fixed cardiac catheterization

We have documented evidence that requiring travel outside the service area automatically deters a substantial proportion of our residents from follow up on treatment or diagnostic recommendations. Patient reasons for deferral involve their perception of distance from home to the treatment center, fear of travel on the interstate and urban beltways, and distance of the referral center from family and support networks. We cannot address their concerns for every specialized service. However, the shared cardiac catheterization laboratory is uniquely suited to address care in a small market. The same disease that causes cardiac circulatory problems causes peripheral circulatory problems. The tool for finding and treating both is the same equipment.

The advent of multi-slice computed tomography (CT) introduced coronary artery CT as a diagnostic alternative. However, by current indications, the new modality is truly an adjunct, not a replacement for cardiac catheterization. CT cannot provide sufficient specificity for a definitive treatment plan. According to a May 2007 article written by the founding members of the Society for Cardiovascular Computed Tomography, David Allie, MD, et al "angiography is most valuable for identifying risk in an asymptomatic population."

Our lab would first have to establish a long record of safety with excellent clinical outcomes before consideration of more urgent procedures. That being said we believe the availability of angiography in our community will increase the awareness of the life-threatening consequences of atherosclerosis and it is our hope this will lead to an increased awareness, recognition and diagnosis and more importantly definitive care.

Often, patients who choose to live in rural communities such as ours feel they make this decision at the expense of healthcare. Patients in rural communities should have the same access to leading edge healthcare technologies as those living in larger metropolitan areas. An angiographic suite and cardiac catheterization laboratory will assist us in taking great strides toward achieving this goal.



DPS HEALTH PLANNING  
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JUL 24 2007

Medical Facilities  
PLANNING SECTION

Good afternoon, my name is Michael Joyner and I am a Registered Nurse and manager of cardiac services for the nursing division at Halifax Regional. Having worked almost exclusively in northeastern North Carolina for 25 years, I have firsthand knowledge of the extent vascular disease affects our rural communities.

Halifax Regional will be working closely with an interventional cardiologist who also has received training in cardiac and vascular disease in eastern North Carolina. Dr. Geloo's training in both coronary and peripheral vascular disease will offer a new and unique perspective to Roanoke Rapids and the population within the surrounding communities.

Atherosclerosis is a systemic disease that can lead to devastating acute and long term consequences and is consistently among our top 10 DRGs for hospital admission. Dr. Geloos' unique training will afford us the opportunity to focus on the disease and the patient as a whole rather than focusing on individual processes.

This approach to disease management is an important one in that all of these diseases are interrelated. A patient with poor circulation to the lower extremities is at an increased risk for heart attack and death; conversely a patient with coronary disease is at significant risk for stroke. These relationships are well documented by research and epidemiology trials. In many cases these disease states will require invasive angiography for definitive diagnosis.

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Peripheral arterial disease is routinely under-diagnosed and it is our belief that neighboring tertiary facilities will see an increase in the number of referrals from Halifax as a result of our expanded focus on atherosclerosis.

This alone will substantially advance Halifax Regional's capability to serve

Greensboro PH  
7-20-07  
Cardiac Cath  
Tom

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Medical Facilities  
Planning Section

**Supplemental Information for Petitions filed by Halifax Regional Medical Center  
and Scotland Memorial Hospital for Special Need Determination for Shared Fixed  
Cardiac Catheterization Laboratories in Halifax and Scotland Counties.**

***Petitioner 1:***

Halifax Regional Medical Center  
250 Smith Church Road  
Roanoke Rapids, NC 27870

***Contact 1:***

William Mahone, V  
President  
Halifax Regional Medical Center  
250 Smith Church Road  
Roanoke Rapids, NC 27870  
(252) 535-8011

***Petitioner 2:***

Scotland Memorial Hospital  
500 Lauchwood Drive  
Laurinburg, NC 28352

***Contact 2:***

Gregory C. Wood  
President and CEO  
Scotland Memorial Hospital  
500 Lauchwood Drive  
Laurinburg, NC 28352  
Ph: 910-291-7501

The following information provided by Phillips shows the contents of a "cardiac package" that can be acquired and installed on an angiography laboratory to render it capable of producing high quality cardiac catheterization. Note that the angiography laboratory camera is designed with a wide field needed to view a peripheral vascular bed. The cardiac package provides hardware and software to narrow the camera aperture and increase the shutter speed to handle the requirements of a beating heart. The estimated cost of a package like this is approximately \$200,000. Thus, the adaptation costs of a shared lab make this a highly cost effective solution for a rural area.

By contrast, typically a cardiac catheterization laboratory has only the narrow aperture camera. The current MedCath laboratories are narrow aperture labs.

- |   |   |   |
|---|---|---|
| 1   | <b>**NNAE085      Allura Xper FD20 Card Sys</b> | 1 |
| <p>The Allura Xper FD20 Cardiac single plane cardiovascular system is comprised of a ceiling mounted stand and digital imaging X-ray system for cardiovascular diagnostic and interventional procedures</p> |   |   |

The Allura Xper FD20 system uses an integrated single-host concept. The system is comprised of five functional building blocks: Geometry, X-ray Generation, User Interface, Image Detection, and Viewing. Each functional building block is explained in further detail.

**Xres Cardiac (NCVA664)**

- Xres Cardiac enhances sharpness, contrast, and reduces noise in fluoroscopy and exposure runs for cardiac studies

DFS Health Planning  
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AUG 03 2007

MEDICAL FACILITIES  
PLANNING SECTION

4	<b>**NCVA118</b>	<b>Ventricular Quantification SW Pkg (Xper)</b>	1	<b>\$12,060.00</b>	<b>\$12,060.00</b>
		Calculates the Ejection Fraction and local Wall Motion parameters in different formats. Functions include: Various LV-volumes Ejection Fraction Cardiac Output Centerline Wall Motion Slager Wall Motion Regional Wall Motion Calibration routines			
5	<b>**NCVA119</b>	<b>Coronary Quantification SW Pkg (Xper)</b>	1	<b>\$5,695.00</b>	<b>\$5,695.00</b>
		Functions include: Diameter measurement along the selected segment; Densitometric information; Cross sectional area; percent stenosis; Pressure gradient values; Stenotic flow reserve; Calibration routines			
6	<b>**NCVA121</b>	<b>FULL AUTOCAL</b>	1	<b>\$5,360.00</b>	<b>\$5,360.00</b>
		The AutoCal option is a software package to be used in conjunction with quantitative analysis software packages. It provides an auto calibration procedure for an object to be analyzed that is placed in the iso-center. When the object to be analyzed (e.g. Left Ventricle Vessel Segment) is placed in the iso-center AutoCal avoids the need to: - acquire an additional image series containing a sphere or grid for calibration purposes - calibrate manually on a calibration object (e.g. catheter) displayed in the image or image series to be analyzed			
7	<b>**NCVA660</b>	<b>3D-RA R.5</b>	1	<b>\$51,925.00</b>	<b>\$51,925.00</b>
		Allura 3D-RA is designed to provide three dimensional images of brain and peripheral vessels			
		<b>Image Acquisition</b> Image acquisition is performed with the Rotational Angiography feature of the Allura Xper FD series with the flexibility to position the C-arm in either head or side position  - C-arm in Head position: the Rotational Angiography run is performed over a scan range of 240 degrees with a rotation speed up to 55 degrees/sec			
10	<b>**NCVA116</b>	<b>3D RA Control for Xper Module</b>	1	<b>\$10,720.00</b>	<b>\$10,720.00</b>
		Table Side Module functionality for Allura Xper FD20 used with Integris 3D-RA Release 4.2. For further improvement of interventional procedures efficiency the following workflow enhancers are made available in the examination room: With the Xper touchscreen module the physician has all 3D functionality needed at bedside. Functionality like rotating panning zooming AVA Virtual stenting 3 and 3D Follow C-arc can be performed. No need for the Physician to leave the examination room. 3D Automatic Position Control (3D-APC), when the optimal working position has been chosen via the Integris 3D-RA interventional tool the C-arc will automatically steer to this position 3D Follow C-arc: When the position of the C-arc (not using any X-ray) is changed the 3D volume will automatically follow the position of the C-arc. This means the position of the C-arc (and therefore the 2D projection) and the 3D volume are always aligned.			

13	**NCVA675	3D Roadmapping	1	\$52,260.00	\$52,260.00
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This extends the capabilities of the integrated 3D product by providing a sustainable 3D roadmap to support interventional procedures.

The 3D Roadmap option matches the real-time 2D fluoro images with the 3D reconstruction of the vessel tree. So one can see the advancement of the guide wire, catheter and coils on the 3D volume in real time.

The 3D roadmap will remain if one changes the C-arm position, the SID and/or the Field of View of the flat detector. The 3D volume will follow automatically the orientation of the C-arm, providing the flexibility to chose the optimal position of the C-arm.